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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,222	12/20/2001	Ranjani V. Parthasarathy	57314US002	9052

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EXAMINER

YOUNG, JOSEPHINE

ART UNIT	PAPER NUMBER
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1623

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DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,222

Applicant(s)

PARTHASARATHY ET AL

Examiner

Josephine Young

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-38, drawn to methods of removing small negatively charged organic molecules from a biological sample mixture obtained from nucleic acid amplification reactions or nucleic acid labeling reactions using an anion exchange material, classified in class 536, subclasses 25.4, 25.41 and 127.
- II. Claims 39-52, drawn to devices and analytical receptacles comprising an anion exchange material, classified in class 436, subclasses 111, 113, 177 and 178.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of Group I can be practice by another materially different apparatus or by hand. In particular, the device or analytical receptacle of Group II is not required to practice the process of Group I as evidenced by claims 1-16, wherein the removal of the small negatively charged organic molecules from a biological sample mixture is accomplished by simply using an using an anion exchange material, not specifically limited to the device or analytical receptacle of Group II.

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Therefore, the process does not render obvious the device or analytical receptacle. The different groups are directed to patentably distinct inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A reference for one group could not reasonably be expected to be a reference for the other. Further, searching both of the inventions constitutes a burdensome search, as a thorough search comprises a search of foreign patents and non-patent literature, as well as the appropriate U.S. patent classifications. To search the two independent and distinct inventions, set forth supra, would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Election of Species

If Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-38 of Group I are generic.

Group I of this application contains claims directed to the following patentably distinct species of the claimed invention: method of removing small negatively charged organic

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molecules from a biological sample mixture obtained from nucleic acid amplification reactions or nucleic acid labeling reactions using an anion exchange material,

wherein the small negatively charged organic molecule is selected from one of the following:

(AA): the small negatively charged organic molecule is a primer;

(AB): the small negatively charged organic molecule is a nucleoside or nucleotide dye-labeled terminator;

(AC): the small negatively charged organic molecule is a non-nucleoside and non-nucleotide dye-labeled terminator;

(AD): the small negatively charged organic molecule is a degraded dye molecule; or

(AE): the small negatively charged organic molecule is a nucleotide triphosphate;

AND wherein the anion exchange material is selected from one of the following:

(BA): the anion exchange material is not in an array, does not comprise quaternary ammonium ions and is not coated with a negatively charged polymer;

(BB): the anion exchange material is not in an array, does not comprise quaternary ammonium ions and is coated with a particular negatively charged electrolyte;

(BC): the anion exchange material is not in an array, does not comprise quaternary ammonium ions and is coated with a particular negatively charged non-electrolyte polymer;

(BD): the anion exchange material is not in an array, comprises quaternary ammonium ions and is not coated with a negatively charged polymer;

(BE): the anion exchange material is not in an array, comprises quaternary ammonium ions and is coated with a particular negatively charged electrolyte;

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- (BF): the anion exchange material is not in an array, comprises quaternary ammonium ions and is coated with a particular negatively charged non-electrolyte polymer;
- (BG): the anion exchange material is in an array, does not comprise quaternary ammonium ions and is not coated with a negatively charged polymer;
- (BH): the anion exchange material is in an array, does not comprise quaternary ammonium ions and is coated with a particular negatively charged electrolyte;
- (BI): the anion exchange material is in an array, does not comprise quaternary ammonium ions and is coated with a particular negatively charged non-electrolyte polymer;
- (BJ): the anion exchange material is in an array, comprises quaternary ammonium ions and is not coated with a negatively charged polymer;
- (BK): the anion exchange material is in an array, comprises quaternary ammonium ions and is coated with a particular negatively charged electrolyte; or
- (BL): the anion exchange material is in an array, comprises quaternary ammonium ions and is coated with a particular negatively charged non-electrolyte polymer;

such that each independent species is directed to a distinct small negatively charged organic molecule (AA-AE) AND a distinct anion exchange material (BA-BL).

If Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 39-52 of Group II are generic.

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Group II of this application contains claims directed to the following patentably distinct species of the claimed invention:

(AA): device with a plurality of process arrays, such that the surface within at least one process array comprises an anion exchange material; or

(AB): analytical receptacle with one or more reservoir and a surface with a cover film, such that the cover film has an adhesive comprising an anion exchange material;

AND wherein the anion exchange material is selected from one of the following:

(BA): the anion exchange material is not in an array, does not comprise quaternary ammonium ions and is not coated with a negatively charged polymer;

(BB): the anion exchange material is not in an array, does not comprise quaternary ammonium ions and is coated with a particular negatively charged electrolyte;

(BC): the anion exchange material is not in an array, does not comprise quaternary ammonium ions and is coated with a particular negatively charged non-electrolyte polymer;

(BD): the anion exchange material is not in an array, comprises quaternary ammonium ions and is not coated with a negatively charged polymer;

(BE): the anion exchange material is not in an array, comprises quaternary ammonium ions and is coated with a particular negatively charged electrolyte;

(BF): the anion exchange material is not in an array, comprises quaternary ammonium ions and is coated with a particular negatively charged non-electrolyte polymer;

(BG): the anion exchange material is in an array, does not comprise quaternary ammonium ions and is not coated with a negatively charged polymer;

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- (BH): the anion exchange material is in an array, does not comprise quaternary ammonium ions and is coated with a particular negatively charged electrolyte;
- (BI): the anion exchange material is in an array, does not comprise quaternary ammonium ions and is coated with a particular negatively charged non-electrolyte polymer;
- (BJ): the anion exchange material is in an array, comprises quaternary ammonium ions and is not coated with a negatively charged polymer;
- (BK): the anion exchange material is in an array, comprises quaternary ammonium ions and is coated with a particular negatively charged electrolyte; or
- (BL): the anion exchange material is in an array, comprises quaternary ammonium ions and is coated with a particular negatively charged non-electrolyte polymer;

such that each independent species is directed to either a device or an analytical receptacle (AA-AB) **AND** a distinct anion exchange material (BA-BL).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

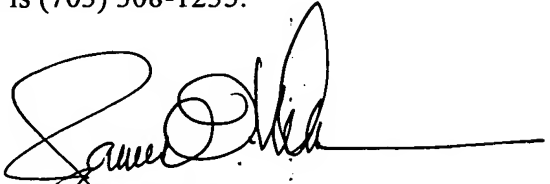
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
April 19, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600